



EPA RESPONSES TO LATAG COMMENTS ON THE CONCEPTUAL SITE MODEL (CSM) FOR OU4

- Cover letter: for clarification, it is **Hazard Identification** that is the conventional 1st step in the BLRA, as described by the National Academy of Sciences seminal publication on BLRA.
 - Hazard ID typically involves selection and characterization of preliminary chemicals of concern (COCs), screening-level sampling and screening-risk analyses, method evaluation or development (to get quantitative data [sic] with MDLs and MQLs below RBCs), initial scoping of site work and estimates of the nature and extent of contamination by suspected risk-driving COCs; the CSM generally follows as a subsequent step after the Hazard ID – as opposed in the cover letter and initial pages of the draft CSM report;

Response: The risk assessment paradigm utilized at Superfund sites is presented in Exhibit 1-2 of *Risk Assessment Guidance for Superfund (RAGS), Part A* (USEPA 1989). While it shares many concepts with the National Academy of Sciences paradigm, the Superfund paradigm does not involve a step referred to as Hazard Identification. Rather, the Superfund process begins with the Data Collection and Evaluation step, the purpose of which is to determine what chemicals are present at a site and which are likely to be of human health concern. Following this step, two processes occur in parallel: Exposure Assessment and Toxicity Assessment. The purpose of the Exposure Assessment step is to identify potential exposure pathways that may be occurring at the site, to select which of these require quantitative evaluation, and to derive quantitative estimates of human exposure for each of the exposure scenarios selected. The Toxicity Assessment step involves collection of data on the toxicity effects of a chemical and any available information on exposure-response relationships. The final step of the Superfund risk assessment paradigm is Risk Characterization, where the results from the Exposure Assessment and Toxicity Assessment are combined.

As discussed in Chapter 4 of *RAGS Part A* (USEPA 1989), the Conceptual Site Model (CSM) is developed during the first step of the Superfund risk assessment process, Data Collection and Evaluation. Guidelines relevant to this first step can be found in EPA's Data Quality Objectives (DQO) Guidance (EPA 1987a, b). In the first stage of the DQO process, all available site information is compiled and analyzed in order to develop a conceptual model of the site that describes suspected sources, contaminant pathways, and potential receptors. Thus, in accord with the DQO process, the CSM should be developed early in the risk assessment process, usually as soon as data begin accumulating on the types and levels of chemicals observed in various site media.

Several Technical Guidance documents developed in Region 8 also underscore the importance of early CSM development (USEPA Region 8 1994, 1995). Notably, the CSM often helps guide subsequent data collection efforts, which then help refine the CSM in an iterative fashion. Thus, in accord with Superfund

guidance and regional guidelines, the CSM is developed during the first step in the risk assessment process, Data Collection and Development, and characterization of the CSM as an early step in the risk assessment is valid.

- also, LA is not fully characterized yet for toxic structures sizes, fragmentation hazards, and internal fates.

Response: EPA agrees that the toxicity of asbestos, including Libby amphibole (LA), is not yet fully resolved, and the Agency is working to advance both cancer and noncancer toxicity models on several fronts. This is generally an activity that occurs on the national level, and only rarely at the site level.

- While it is good for EPA to “consider” comments, LATAG should also request and expect to receive **responses and actions taken** to address those comments in a revised report.

Response: This document serves as EPA’s response to the LATAG.

- Page 1: “**exact geographical areas**” of **ALL OUs** are **unknown** or uncertain because:
 - EPA R8 does not have site-related, confident, risk-based concentrations (**RBCs**) nor credible preliminary remediation goals (**PRGs** - *remedial*, **not removal**, clean-up numbers) at this time due to lack of adequate quantities, qualities, or relevance of site data

Response: Selection of Operable Units (OUs) is mainly a matter of administrative convenience, and not necessarily one of risk assessment considerations. More specifically, OUs are usually selected so that data gaps and issues that may limit headway for one location or one medium do not hold up progress in another location or medium. As defined by the National Contingency Plan (NCP), “Operable Units may address geographical portions of a site, specific site problems, or initial phases of an action, or may consist of any set of actions performed over time or any actions that are concurrent but located in different parts of a site” (NCP 1994). The designation of OUs typically does not require RBCs or PRGs, and does not even require data on the level of site contamination (although this may be considered in some cases). At the Libby Superfund Site, the determination of OUs is based on both functional use and geographic location.

- Studies have mostly been conducted under sampling and analyses plans (SAPs) for **other investigational purposes** that generally preclude their full quantitative use, due to lack of spatial and temporal **representativeness** and limited quality assurance/control (**QA/QC**); e.g., PARCC - precision, accuracy, reproducibility, completeness, consistency.

Response: EPA is presently performing a detailed data adequacy evaluation to assess the usability of data that have been collected for potential use in the risk assessment. This includes an evaluation of temporal and spatial

representativeness, as well as other key data usability criteria (e.g., data sources, sample collection procedures, analytical methods and detection limits, completeness, comparability, representativeness, precision, and accuracy). In this regard, it is important to note that the purpose for which a study was performed does not inherently determine the usability of the resulting data. Rather, the properties of the data collected determine their usability, either for their “intended” purpose, or for other purposes (USEPA 1989, USEPA 1992).

- **Risk-based boundaries** can be readily determined by routine sampling and analyses after EPA determines site-specific RBCs in media for major land-use scenarios, from:
 - **Cancer slope factors** for Libby amphibole (LA) asbestos derived from **toxicity studies on relative potency compared to the chrysotile standard**
 - **Non-cancer toxicity** benchmarks for inflammatory diseases (e.g., pleural fibrosis) and for possible auto-immune diseases (e.g., lupus, rheumatoid arthritis, etc.).
 - **Cumulative** exposure ranges from all major exposure pathways that contribute the majority of risks, including the possibility of using available **clinical exposure data**

Response: The phrase “risk based boundaries” is not a standard term in Superfund risk assessment and the meaning is not entirely clear. As stated above, the determination of OUs at the Libby Site is based on functional use and geographic location.

Delineation of areas of the Site that are of concern to humans cannot be accomplished by simply comparing environmental concentration values to risk-based concentration (RBC) values computed from cancer and noncancer toxicity values. First, as noted above, there is some level of on-going scientific debate regarding the most appropriate cancer and noncancer risk models and toxicity values. Development of new toxicity values is a long-term process that may involve a) careful planning and implementation of animal toxicity studies designed to yield useful information; b) analysis of data from animal toxicity studies and/or human occupational/environmental epidemiological studies; c) derivation of toxicity values; and e) extensive peer review. EPA believes that postponing delineation of the Site into OUs pending availability of peer-reviewed toxicity values will unnecessarily delay progress at the Site.

Second, calculation of RBCs requires human exposure parameters, some of which are not currently known with confidence. Because EPA R8 prefers to use reliable Site-specific data rather than standard default inputs that may not accurately represent Site receptor exposures, an activity survey of OU4 human receptors is planned to address this data gap.

Third, EPA strongly supports evaluation of cumulative exposures in cases where multiple exposure pathways exist. The Baseline Risk Assessment (BRA) for OU4 will incorporate a cumulative assessment of risk from multiple pathways of exposure.

Although RBCs will not be used to establish OUs at the Libby Site, EPA does intend to utilize RBCs to help recognize media and locations of possible or probable concern, and in the determination of final Site-specific cleanup standards, which will be established upon the completion of the RI/FS and publication of a Record of Decision.

- **Ecological** risk assessment and **biomonitoring** needs should be discussed in CSM context

Response: An ecological risk assessment will be performed on a Site-wide basis as part of the OU3 (mine) investigation.

- Page 2: the first paragraph mentions investigations on “nature and extent” of contamination, which also assist in establishing risk-based boundaries for various OUs, but which are uncertain
 - Para. 2 states a common and persisting **misnomer about “clean-up of properties”** under EPA’s ER authority, which correctly conducts “**partial removals**” and **leaves residual contamination** that does not exceed a threshold for imminent and substantial health threats

Response: This statement is not necessarily correct. Removal actions need not be partial and need not be linked to an imminent and substantial endangerment. To the contrary, cleanup actions taken at the Site to date have reduced exposures and risk and, to the extent practicable, have minimized the likelihood that a medium that has undergone a cleanup will require additional cleanup. However, final decisions regarding risks from any residual contamination must await the completion of the BRA.

- Para. 2 also describes “current” conditions, but **past** (e.g., Libby Dam workers –at their jobs and in Libby, former residents who contacted LA in past occupational settings, etc.) and **future** (under **changing land-use scenarios**) exposures need to be considered for a reasonably complete and protective BLRA that more accurately predicts potential risks

Response: As noted in the text, the BRA will, to the extent possible, evaluate risks as they existed in Libby in approximately 1999 (before EPA began any cleanup activities), and risks that exist after cleanup has occurred. Note that Superfund does not typically investigate or characterize the level of risks that may have existed in the past, since EPA has no authority to take action unless current and/or future exposures are above a level of health concern. However, EPA recognizes that historical conditions may have contributed to increased LA tissue

burdens in receptors in OU4. Therefore, in the BRA, EPA will not attempt to quantitatively reconstruct historical occupational exposures, but will discuss in a qualitative manner their potential impact on OU4 receptors. Reasonable future land use scenarios will also be considered in the OU4 BRA.

- Para. 3 correctly notes the **limited scope** of this draft CSM as only pertaining to inhalation at OU4, and it mostly deals with current suspected exposure pathways, not past or future

Response: As noted above, the CSM is restricted to inhalation exposure pathways in OU4 because it is believed that any risks from oral pathways are likely to be much smaller than risks from inhalation. EPA acknowledges that ingestion pathways represent a plausible means of exposure. However, because the magnitude of risk associated with these pathways is likely to be small compared to risks from inhalation pathways, evaluation of the latter has been prioritized from a risk management perspective. Recognize that current EPA actions to address inhalation exposure pathways also are likely to reduce or eliminate exposures associated with many potential ingestion pathways. Additionally, EPA is limited in the tools currently available for addressing ingestion pathways because: a) no validated oral slope factor is available, and b) calculation of risks would require estimates of concentration (in units of structures/gram) in soil and dust, which are not provided by the current analytical methods.

Additionally, in accord with Superfund policy, the CSM will consider both current and hypothetical future exposure scenarios in OU4. Historical exposures will be addressed qualitatively as described above.

- **Other media and routes** of exposure, not mentioned elsewhere, may include ingestion of home-grown produce, or swallowing inhaled LA from the “tracheal mucous escalator”

Response: The text notes that oral exposure pathways may occur and may contribute to risk, but that these pathways are not included in the CSM because these pathways are judged to be of substantially lesser concern than the inhalation pathways.

- Para 4: EPA should **define vague terms** such as: *complete, significant, magnitude, relative, strength vs weight of evidence*, etc.

Response: These terms are used in their normal context.

- Page 3: transportation related sources and releases of LA should be included, and the specific OUs that fall into the 4 categories of sources should be identified
 - #2. **Vegetation** surfaces and internal parts should be considered for LA contamination

Response: The CSM is specific to OU4. Sources and releases pertinent to other OUs will be addressed in their respective OU. Transportation related sources and releases of LA are included in items 3 and 4 (“Solid Wastes” and “Vermiculite Product”). Additionally, as noted above, the CSM addresses only inhalation pathways, not ingestion pathways. EPA is not aware of any data indicating that solid particles of LA are taken up into internal tissues of vegetation.

- #3. **future** releases need consideration, as well as **forests, roadways, riparian** areas

Response: As noted above, the BRA will consider both current and hypothetical future exposures that are likely to occur in OU4. Forested and riparian areas, as well as roadways, located within OU4 that represent potential exposure areas for current/future residents, workers, or visitors to OU4 will be evaluated. A Site-wide ecological risk assessment will be performed as part of the OU3 (mine) investigation. Future releases will be considered in Institutional Controls and Operations and Maintenance.

- #4. **other sources** of vermiculite products or wastes may include wood, water, other vegetation, surface water and sediments, and possibly locally raised or wildlife meats

Response: The CSM currently includes burning of contaminated wood (tree bark) as a possible exposure pathway. The current version of the CSM also includes “Surface Water Runoff” and “Sediment” as release and transport pathways. As noted above, the CSM will address inhalation pathways only; ingestion of water, vegetation, or locally raised livestock or wildlife will not be included.

- Page 4: rationale for migration of solids to remain in place needs rewording and discussion of migration of **fibers** as an exception, due to their ability to disperse as suspended particles in air
 - #3. **Hauling** can involve both intentional and unknowing transfer of contaminated media

Response: Rationale for migration of solids to remain in place will be clarified. EPA agrees that hauling of contaminated soil may be either intentional or unknowing. However, the state of knowledge of the hauler has no impact on subsequent exposures and risks from the contaminated medium after it is put in place.

- Populations – Residents: activities should include evaluation of **gardening**, do-it-yourself **remodelers** or handymen/women, handling and local disposing of **contaminated wood** from saw dust and stove **ash**; again, for both **past and future** individuals

Response: Gardening by residents is included in the soil disturbance pathway. Home remodeling is covered in the breached walls pathway. Disposal of potentially contaminated ash will be added to the CSM as a possible exposure pathway. Exposures to contaminated tree bark other than those associated with indoor burning (e.g., exposure to sawdust) will be included in the OU3 investigation. As noted previously, the scope of the BRA will include current and future exposures; historic exposures will be addressed qualitatively.

- Page 5: occupational exposures should be distinguished more by **light exposure for commercial** scenarios vs **heavier exposures for the tradesperson**
 - **Part-time or intermittent** exposures should be considered, along with continual contacts, for visiting workers, contractors, and DIY remodelers or handypersons (note: EPA and DOJ supposedly base much of their lawsuit against WR Grace on **short-term** endangerment of federal agents after withholding such information on LA hazards, so if this scenario is substantial enough a concern for short-term EPA contact, why not for others?)

Response: EPA agrees. Many of the exposure scenarios in the CSM that will be evaluated are part-time or intermittent in nature.

- **Trespassers and Agricultural** workers (gardeners or landscapers) are not included

Response: Professional gardeners and landscapers are considered in the “Tradesperson” category. Risks to trespassers at any particular location are not considered because risks to trespassers will be smaller than the risks to the residents or workers who legally utilize the area, now or in the future.

- **ACM** is not discussed for contributions to exposures and risks (Zonolite)

Response: Pathways involving ACM (Zonolite vermiculite insulation) are included in the CSM for indoor locations with unenclosed and enclosed vermiculite insulation. Likewise, to the extent that bulk vermiculite is present as a contaminant in soil, exposures from that pathway are also included.

- **Crawl spaces** should be mentioned as an unenclosed example, along with attics

Response: The CSM will be revised as suggested.

- Page 6: para 3 should include **other** residential structures; e.g., garages, shops, sheds, barns, etc.
 - **Background** contamination of LA needs to be determined for levels and relative risks

Response: The text will be revised to include other residential structures. EPA agrees that an understanding of “background” levels of LA in air, soil, and dust is important, and is working to obtain data that will allow an estimation of these levels.

- Last para. (pg 7) should include vehicles and cumulative exposures outside of OU4 also

Response: As stated in the text, the CSM covers only pathways that are associated with OU4; exposure pathways associated with other OUs will be evaluated in separate documents.

- **Fires** are not included, but were in Sep 06 draft CSM

Response: The CSM will be amended to include structural fires. However, because such fires are rare events and releases would only occur for brief periods, EPA considers this to be a relatively minor source of risk, and does not intend to seek to collect data to support quantitation of this pathway.

- **Mowing and digging** in yards was also in earlier draft, but absent here

Response: Mowing and digging are included in the soil disturbance pathway.

- **Libby Dam and Libby mine contributions** to LA exposures (workers, spouses, children) should be considered as mixed exposures for properly evaluating cumulative risks

Response: Historic exposures of workers and their families will be addressed qualitatively the OU4 BRA as described above. If a location is contaminated because of material brought home by a former worker, that contamination is included in the assessment of current risks.

- Figure 2: what boxes depict **data-gaps and uncertainties**, and how will they be addressed?

- **Transportation** is a source and release mechanism

Response: Data gaps will be addressed in a report detailing EPA’s current data mining effort (to be shared with the public). Uncertainties are not depicted in the boxes on the CSM diagram, but will be addressed in depth in the BRA. Transportation is not a source, but is a transport mechanism. It is so indicated in the CSM.

- **Future** scenarios should be included, and past episodes of higher contributions of LA

Response: In accord with Superfund policy, the CSM considers both current and hypothetical future exposure scenarios in OU4. Historical exposures will be addressed qualitatively in the BRA.

- **Spills** can be local and extended over distances

Response: EPA agrees that if the source of a vermiculite spill is a moving vehicle (truck, train, etc.), then spillage may occur along the route of the vehicle. This is indicated in the CSM.

- Include **fires, mowing, sawdust, home remodeling, contaminated vegetation, meat** etc.

Response: As noted above, house fires will be noted in the CSM as a potential release mechanism, but EPA considers this to be a minor source of concern and does not plan on performing quantitative evaluations of this pathway. Inhalation exposures during tree cutting (sawdust) will be considered in the risk assessment for OU3. Mowing is included in the soil disturbance pathway. Home remodeling is included in the pathway that covers releases from breached walls. Ingestion of vegetation and meat are oral pathways that are judged to be of low concern compared to inhalation pathways.

- Most blank boxes have **no basis to leave blank**, therefore enter ? or else justify status

Response: Blank boxes indicate that the exposure pathway is not complete (i.e., does not occur) or is believed to be negligible (justification for which will be added to the text).

References

USEPA 1987a. Data Quality Objectives for Remedial Response Activities: Development Process. Office of Emergency and Remedial Response and Office of Waste Programs Enforcement. EPA/540/G-87/003. (OSWER Directive 9335.0-7B).

USEPA 1987b. Data Quality Objectives for Remedial Response Activities: Example Scenario: RI/FS Activities at a Site with Contaminate Soils and Ground Water. Office of Emergency and Remedial Response and Office of Waste Programs Enforcement. EPA/540/G-87/004.

USEPA 1989. RAGS A. Risk Assessment Guidance for Superfund. Volume I. Human Health Evaluation Manual (Part A). U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. EPA/540/1-89/002.

USEPA 1992. Guidance for Data Useability in Risk Assessment (Part A). Office of Emergency and Remedial Response. Publication 9285.7-09A.

USEPA 1994. National Oil and Hazardous Substances Pollution Contingency Plan. Section 300.5.

USEPA Region 8 1994. Statement of Work for BRA. Model Statement of Work for RI/FS Baseline Risk Assessments of Human Health. Region 8 Superfund Technical Guidance RI/FS No RA-01.

USEPA Region 8 1995. Model Site Conceptual Model for RI/FS Baseline Risk Assessments of Human and Ecological Health. Region 8 Superfund Technical Guidance No. RA-05.